

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

THE STATE OF IOWA, ex rel.  
THOMAS J. MILLER,  
ATTORNEY GENERAL  
99AG25112

Plaintiff,

vs

ASTRAZENECA PHARMACEUTICALS, LP

and

ASTRAZENECA LP,

Defendants.

PETITION

Equity No. 68028

FILED  
POLK COUNTY, IA  
12 MAR 10 AM 8:18  
JEREM DISTRICT COURT

INTRODUCTION

Plaintiff, the State of Iowa ex rel. Attorney General Thomas J. Miller, by Special Assistant Attorney General William L. Brauch, brings this action complaining of Defendants AstraZeneca Pharmaceuticals, LP, and, and AstraZeneca LP, for violating the Iowa Consumer Fraud Act, Iowa Code section 714.16, as follows:

JURISDICTION AND VENUE

1. This action is brought by the State of Iowa ex rel. Attorney General Thomas J. Miller, pursuant to the provisions of the Iowa Consumer Fraud Act, Iowa Code section 714.16.

2. This Court has jurisdiction over the Defendants pursuant to Iowa Code section 714.16, because the Defendants have transacted business within the State of Iowa at all times relevant to this Petition.

3. Venue for this action properly lies in Polk County, Iowa, pursuant to Iowa Code section 714.16 (10), because Defendants transact business in Polk County, Iowa and/or some of the transactions out of which this action arose occurred in Polk County, Iowa.

### **PARTIES**

4. The Attorney General of Iowa is charged, inter alia, with the enforcement of the Consumer Fraud Act, Iowa Code section 714.16(7).

5. AstraZeneca Pharmaceuticals LP and AstraZeneca LP (hereinafter "AstraZeneca") are the Defendants in this case. AstraZeneca's Corporate Headquarters is located at, 1800 Concord Pike, Wilmington, DE 19850-5437. As used herein, any reference to "AstraZeneca" shall mean Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP. AstraZeneca transacts business in Iowa and nationwide by manufacturing, marketing, promoting, selling and distributing prescription drugs, including Seroquel.®

### **ADVERTISING AND SELLING MERCHANDISE IN IOWA**

6. Iowa Code § 714.16(2)(a) applies to the sale, lease or advertisement of merchandise in the State of Iowa. Defendants were at all times relevant hereto, engaged in the advertisement and sale of merchandise in the State of Iowa to wit: advertising, soliciting, offering for sale and selling prescription drugs, including Seroquel, and accepting monies from Iowa consumers for the same.

### **BACKGROUND**

7. AstraZeneca manufactures, markets, and promotes Seroquel nationally and in Iowa. Seroquel is a drug classified as an atypical antipsychotic.

8. While some experts hypothesized, as early as 1993, that atypical antipsychotics may reduce some of the side effects that traditional antipsychotics cause, there were early signs that these drugs, including Seroquel, produced dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications and other severe conditions.

9. Seroquel received approval from the U.S. Food and Drug Administration (hereinafter "FDA"), for the treatment of manifestations of psychotic disorders, including schizophrenia, on September 26, 1997.

10. FDA narrowed Seroquel's label to "indicated for the treatment of schizophrenia" on March 27, 2001.

#### **ASTRAZENECA'S MARKETING OF SEROQUEL**

11. Iowa permits physicians to prescribe FDA-approved drugs for conditions or diseases for which FDA approval has not been obtained when, through the exercise of independent professional judgment, the physician determines the drug in question is an appropriate treatment for an individual patient. This practice is referred to as "off-label prescribing."

12. However, pharmaceutical manufacturers may not promote or market their products for any use not specifically approved by the FDA. This practice is known as "off-label marketing."

13. Before late 2009, Seroquel was approved by the FDA only for the treatment of certain specific conditions in adults, primarily conditions related to Schizophrenia and Bipolar Mania.

14. Despite having narrow FDA approval for adults only, AstraZeneca promoted and marketed the drug for the treatment of a variety of conditions and to a variety of patient populations not included among the FDA-approved indications, including for the treatment of anxiety, depression, sleep disorders, and post traumatic stress disorder, and to child and geriatric populations.

15. Through this off-label marketing, AstraZeneca aimed to enhance Seroquel's market penetration across a wide range of diagnoses and patient populations.

16. AstraZeneca promoted Seroquel's use in children and adolescents long before establishing that it was safe or effective for any use in this population.

17. AstraZeneca promoted Seroquel to treat dementia and Alzheimer's Disease in the elderly even though Seroquel has never been approved for the treatment of these conditions and AstraZeneca has not established that Seroquel is safe and effective for these uses.

18. AstraZeneca also masked, withheld, or failed to disclose negative information contained in scientific studies concerning the safety and efficacy of Seroquel.

19. AstraZeneca failed to adequately disclose the risks associated with Seroquel's use by, among other things, minimizing the risk of hyperglycemia and diabetes mellitus and failing to communicate important information regarding neuroleptic malignant syndrome, tardive dyskinesia, and the risk of bolded cataracts.

#### **APPLICABLE STATUTES**

20. Iowa Code section 714.16(2)(a), states in relevant part as follows:

The act, use or employment by a person of an unfair practice, deception, fraud, false pretense, false promise, or misrepresentation, or the concealment, suppression, or omission of a material fact with intent that others rely upon

the concealment, suppression, or omission, in connection with the lease, sale, or advertisement of any merchandise or the solicitation of contributions for charitable purposes, whether or not a person has in fact been misled, deceived, or damaged, is an unlawful practice.

21. As used in the Consumer Fraud Act, the term "person" includes:

any natural person or the person's legal representative, partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesperson, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof.

Iowa Code section 714.16(1)(j).

22. Neither all nor any part of the application for injunctive relief herein has been previously presented to or refused by any court or justice. Iowa R. Civ. P. 1.1504.

23. In an action by the state, no security shall be required of the state. Iowa R. Civ. P. 1.207.

### **VIOLATIONS OF LAW**

#### **IOWA CONSUMER FRAUD ACT**

24. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs 1 through 21.

25. AstraZeneca, in the course of marketing, promoting, selling, and distributing the prescription drug Seroquel has engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore, has engaged in practices that are unlawful under Iowa Code section 714.16(2)(a) by promoting Seroquel for uses that have not been shown to be safe or effective and by failing to adequately disclose the risks associated with Seroquel's use.

## REMEDIES

26. Iowa Code § 714.16(7), in relevant part, provides:

If it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in a practice declared to be unlawful by this section, the attorney general may seek and obtain in an action in a district court a temporary restraining order, preliminary injunction, or permanent injunction prohibiting the person from continuing the practice or engaging in the practice or doing an act in furtherance of the practice. The court may make orders or judgments as necessary to prevent the use or employment by a person of any prohibited practices, or which are necessary to restore to any person in interest any moneys or property, real or personal, which have been acquired by means of a practice declared to be unlawful by this section, including the appointment of a receiver in cases of substantial and willful violation of this section. . . . .

. . . . . In addition to the remedies otherwise provided for in this subsection, the attorney general may request and the court may impose a civil penalty not to exceed forty thousand dollars per violation against a person found by the court to have engaged in a method, act, or practice declared unlawful under this section; provided, however, a course of conduct shall not be considered to be separate and different violations merely because the conduct is repeated to more than one person. In addition, on the motion of the attorney general or its own motion, the court may impose a civil penalty of not more than five thousand dollars for each day of intentional violation of a temporary restraining order, preliminary injunction, or permanent injunction issued under authority of this section. A penalty imposed pursuant to this subsection is in addition to any penalty imposed pursuant to section 537.6113. Civil penalties ordered pursuant to this subsection shall be paid to the treasurer of state to be deposited in the general fund of the state.

27. Iowa Code section 714.16(10) provides:

In an action brought under this section, the attorney general is entitled to recover costs of the court action and any investigation which may have been conducted, including reasonable attorneys' fees, for the use of this state.

## REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter an order:

A. Issuing a permanent injunction prohibiting Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or

participation with any of them, from engaging in unfair, deceptive or misleading conduct, as provided by Iowa Code section 714.16(7);

B. Ordering Defendants to pay civil penalties of up to \$40,000 for each violation of the Consumer Fraud Act, as provided by Iowa Code section 714.16(7);

C. Ordering Defendants to pay all costs, court costs, and attorney fees for the prosecution and investigation of this action, as provided by Iowa Code sections 714.16(10).

D. Granting such other and further relief as the Court deems equitable and proper.

Respectfully submitted,

STATE OF IOWA ex rel.  
ATTORNEY GENERAL  
THOMAS J. MILLER



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